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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/633,653	08/05/2003	Jan Carlsson	1614-0261P	5460												
7590 Holly D. Kozlowski Dinsmore & Shohl LLP 255 E. 5th Street 1900 Chemed Center Cincinnati, OH 45202		06/19/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">NGUYEN, BAO THUY L</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1641</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>06/19/2007</td><td>PAPER</td></tr></table>		EXAMINER		NGUYEN, BAO THUY L		ART UNIT	PAPER NUMBER	1641		MAIL DATE	DELIVERY MODE	06/19/2007	PAPER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/633,653

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 April 2007 has been entered.
2. Claims 18-21 have been added.
3. Claims 2-21 are pending.

### *Claim Rejections - 35 USC § 112*

4. Claims 2-17 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague with respect to the recitation of the ligand in the separation zone. Does this ligand bind to the analyte? Is it immobilized in the separation zone? The claims is a bit vague because it appears that it is the ligand that is the subject of interest, yet, the recitation of the binding partner for the ligand as the "analyte" leads one to surmise that the "analyte" is the subject of interest.

Claim 2 is also vague because it is unclear how the binding capability of the ligand is determined. Is it a yes/no answer?

Claim 5 is vague with respect to the recitation of "the ligand exhibits one or more positive and/or negative charges in the flow matrix". Does this mean that that ligand only exhibit these charges only when *in* the matrix and not at other time? Furthermore, what kind of ligand has both positive and negative charges?

Claims 9, "the analytically detectable reactant" lacks antecedent support.

Claim 10, "the application zone" lacks antecedent support.

Claims 11 and 17 are vague with respect to the recitation of library members of a chemical library because the metes and bounds of this claim are unclear since the chemical library is not defined.

Claims 12-16, "the analytically detectable reactant" lacks antecedent support.

Claim 21, "the application zone for analytically detectable reactant" lacks antecedent support.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2-21 rejected under 35 U.S.C. 102 (b) as being anticipated by Fitzpatrick et al (US 5,451,504).

Fitzpatrick discloses a device comprising an application zone, a mobilization zone (i.e. application for analytically detectable reactant), a trap zone (i.e. separation zone), a detection zone and an absorbent zone. See figure 1. The mobilization zone comprises labeled receptor for the analyte; the trap zone comprising immobilized ligand that will bind either free receptor or excess analyte. The detection zone comprises immobilized capture reagent for the analyte-labeled receptor complex. See column 4, lines 50-58; column 6, lines 38-44; column 7, lines 15-24, and column 8, lines 13-41. Fitzpatrick is seen to anticipate the claimed test kit because the test kit has nothing more than a device that is taught by Fitzpatrick.

Because the ligand of Fitzpatrick is the same with those of instant claims, i.e. antibodies, therefore, they are expected to exhibit the same characteristics, even though Fitzpatrick does not specifically state that their ligand exhibits a positive and/or negative charge,

Fitzpatrick also does not state that the ligand comprises one or more members of a chemical library, however, since it is unclear what type of library member is being claimed, the various ligands disclosed by Fitzpatrick can clearly be considered members of a library of compounds.

*Response to Arguments*

7. Applicant's arguments filed 26 April 2007 have been fully considered but they are not persuasive.

Applicant argues that Fitzpatrick does not a the separation zone for which the binding capacity of the ligand to an analyte is to be determined because the ligand taught by Fitzpatrick binds to excess labeled reagent and does not bind the analyte.

This argument has been fully considered but is not persuasive. Claims 2 and 18 recite a separation zone containing a ligand. This ligand is not recited as being specific for anything nor is it recited as being able to bind to anything including the analyte. The intended use of the ligand and the device is not given patentable weight since it does not fundamentally change the structure of the claimed invention. The claims are basically directed to a device comprising an application zone, a detection having immobilized affinity capturer, a separation zone containing a ligand disposed between the application zone and the detection zone. Fitzpatrick teaches each and every single structure of this device.

*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


US 2004/0137608

US 2002/0081629

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641 6/7/07